Submitter Information	on SEP 2.7.2	2011
Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749	2011
Contact:	Douglas J. Thistlethwaite	
Date:	March 3, 2011	
Device Name	•	
Classification Name:	System, Imaging, Pulsed Doppler, Ultrasonic	
Classification Number:	90-IYN	
Trade/Proprietary Name:	HI VISION Ascendus Diagnostic Ultrasound Scanner	

#### **Device Intended Use**

Predicate Device(s):

The HI VISION Ascendus is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

HI VISION Preirus Diagnostic Ultrasound Scanner (K093466)

The Modes of Operation of the HI VISION Ascendus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography.

# **Device Description**

#### **Function**

An ultrasound system consists of the following:

- Ultrasound transducer(s) to generate the transmitted ultrasound energy and detect the reflected echoes
- A computer system to control the transducer and analyze the signals resulting from the reflected echoes
- A video monitor with optional image recorder to display the computed image or derived Doppler data

### Scientific Concepts

An acoustic wave is a mechanical perturbation of a medium which passes through a given medium at a fixed velocity. The rate at which the particles in the medium vibrate in the disturbance is the frequency of the wave, and is measure as cycles/second, or hertz (Hz). Frequencies above 20 kHz are not audible, and above this frequency, the acoustic energy is known as ultrasound. For the purposes of medical ultrasound imaging, frequencies in the range of 1-20 MHz are utilized.

The ultrasound waves comprising a beam travel in as straight line in homogeneous media. When an ultrasound wave reaches an interface between two media of different impedances, a portion of the beam energy may pass through the boundary (transmission), and a portion may be reflected. The direction of propagation of the transmitted beam is determined by the angle of incidence of the incident beam upon the boundary, and differences (if any) in the speed of sound in the two media. The direction of reflection is determined solely by the angle of incidence upon the boundary. The relative strength of the reflected wave depends upon the differences in the impedances between the two media. Reflection at a boundary between soft tissue and bone, as an example, involves a large impedance difference, and results in a relatively strong reflected echo. Reflection at a boundary between two soft tissue-types with a relatively small impedance difference, on the other hand, results in a relatively weak reflected echo.

The ultrasound transducer, when operating in pulsed mode, periodically emits an ultrasound burst at a predetermined rate described as the pulse repetition frequency (PRF). During the time duration that the transducer is not transmitting ultrasound energy, it may act as a received for the reflected ultrasound energy. Since the speed of propagation of ultrasound in tissues is estimated as 1540m/sec, the time elapsed between transmission of a pulse and receipt of an echo may be used to estimate the distance from the transducer to the tissue structure giving rise to the reflected echo. The relative strength of the reflected echo can be used to determine the brightness of display of the reflected echo or strength of derived Doppler signal.

### Physical and Performance Characteristics

The principle of operation of ultrasound imaging involves generation of an ultrasound wave with an electric signal applied to a transducer, direction of the resulting ultrasound wave into the tissue of the body, and reception and analysis of the echoes reflected back to the same or an adjacent transducer from the various tissues along the path of the ultrasound wave.

# **Device Technological Characteristics**

The technological characteristics of this device are identical to the primary predicate device. The control and image processing hardware and the base elements of the system software are identical to the predicate device. See Section 4 – Predicate Device Comparison.

#### Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. that HI VISION Ascendus Diagnostic Ultrasound Scanner is substantially equivalent to the predicate devices. In addition, we have concluded that the subject system is substantially equivalent with respect to safety, effectiveness, and functionality to the HI VISION Preirus Diagnostic Ultrasound Scanner (K093466)

#### Attachment

ATTACHMENT	POSITION
Declaration of Conformity with Design Controls	1



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Mr. Doug Thistlethwaite Manager, Regulatory Affairs Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park TWINSBURG OH 44087

SER 2 7 201

Re: K110673

Trade/Device Name: HI VISION Ascendus Diagnostic Ultrasound Scanner

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, and ITX

Dated: August 29, 2011 Received: August 31, 2011

#### Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the HI VISION Ascendus Diagnostic Ultrasound Scanner, as described in your premarket notification:

#### Transducer Model Number

EUP-B512	EUP-CV524	EUP-L53L
EUP-B514	EUP-CV714	<u>EUP-L54MA</u>
EUP-B715	<u>EUP-CV724</u>	<u>EUP-L65</u>
EUP-C511	EUP-ES52E	<u>EUP-L73S</u>
EUP-C514	<u>EUP-ES52M</u>	EUP-L74M
EUP-C524	<u>EUP-F334</u>	<u>EUP-L76</u>
EUP-C532	<u>EUP-F531</u>	EUP-LV74
EUP-C715	<u>EUP-L52</u>	<u>EUP-053T</u>
EUP-CC531	<u>EUP-L53</u>	<u>EUP-054J</u>

<u>EUP-0732T</u>
EUP-OL334
EUP-R54AW-1933
EUP-S50A

EUP-S521
<u>EUP-S70</u> <sup>*</sup>
<u>EUP-S72</u>
EUP-U533

EUP-V53W EUP-VV531 EUP-VV731

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours.

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

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Enclosure(s)

# Indications for Use

510(k) Number (if known): $KU0673$
Device Name: HI VISION Ascendus Diagnostic Ultrasound Scanner
Indications For Use:
The HI VISION Ascendus is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.
The Modes of Operation of the HI VISION Ascendus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography.
Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety  Page 1 of  510K

System:

HI VISION Ascendus

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)		В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	P	P	P	P	P	P	P	
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa	
	Intra-operative (Spec.)	Pb	Pb	_Pb		Pb	Pb	Pb	
	Intra-operative (Neuro.)								
	Laparoscopic	P	P	P		P	P	P	
	Pediatric	P	P	_ P	P	P	P	P	
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd	
	Neonatal Cephalic	P	P	P		P	P	P	
Fetal Imaging	Adult Cephalic	P	P	P	P	P	P	P	
& Other	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph	
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf	
	Trans-urethral						<del>  </del>	<u> </u>	
	Trans-esoph. (non-Card.)						i		
	Musculo-skel. (Convent.)	P	P	P	i	P	P	P	
	Musculo-skel. (Superfic.)	P	P	P		P	P	P	
	Intra-luminal								
	Other (spec.)						i		
	Cardiac Adult	P	P	P	P	P	P	P	
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans esophageal (card.)	Pg	Pg	Pg	P	Pg	Pg	Pg	
	Other (spec.)	<u> </u>		ľ		<u></u>	- 8		
Peripheral	Peripheral vessel	P	Ρ	P	P	P	P	P	
Vessel	Other (spec.)					<del></del>	<del></del>		

N = new indication. P = previously cleared in K093466

#### Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-B512

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	P	Р	P	P	P	P	P	
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa	
	Intra-operative (Spec.) Intra-operative (Neuro.)					·····	- 1	<u>.</u>	
	Laparoscopic								
	Pediatric Small Organ (Spec.)	- 44				_			
	Neonatal Cephalic								
0 0								<del></del>	
& Other	Trans-rectal								
	Trans-vaginal				<u> </u>		ļ .		
	Trans-urethral		_	<u>. </u>					
	Trans-esoph. (non-Card.)						<u> </u>		
	Musculo skel. (Convent.)								
	Musculo-skel. (Superfic.)		<u> </u>						
'	Intra·luminal		_						
i	Other (spec.)								
,	Cardiac Adult			Ì					
Cardiac	Cardiac Pediatric						<u>_</u>		
	Trans esophageal (card.)							. <u></u>	
	Other (spec.)				]	-			
Peripheral	Peripheral vessel								
Vessel	Other (spec.)							_	

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Additional	Comments:
Auditional	Comments.

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-B514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	P	P	P	P	P	P	P	
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa	
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic	·							
	Pediatric					-			
	Small Organ (Spec.)								
	Neonatal Cephalic								
	Adult Cephalic	•							
& Other	Trans-rectal								
	Trans-vaginal							_	
·	Trans-urethral				<u> </u>				
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)							·	
	Other (spec.)								
Peripheral	Peripheral vessel				]				
Vessel	Other (spec.)								

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Additional	Comments:
Anguatonai	Comments

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<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-B715

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

		Mode of Operation							
	ical Application								
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic				-				
	Fetal	P	P	P	P	P	P	P	
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa	
	Intra-operative (Spec.)	-		ļ			<u> </u>		
	Intra operative (Neuro.)						<u> </u>		
	Laparoscopic								
,	Pediatric			<u> </u>			1 1		
	Small Organ (Spec.)						11		
	Neonatal Cephalic		<u> </u>	<u> </u>			ļ		
Fetal Imaging	Adult Cephalic								
& Other	Trans-rectal						<u></u>		
	Trans-vaginal			L			1		
•	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)		<u> </u>						
	Musculo skel. (Superfic.)						<u> </u>		
	Intra-luminal								
	Other (spec.)						1		
	Cardiac Adult			<u> </u>					
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)		İ						
	Other (spec.)		l				<u> </u>		
Peripheral	Peripheral vessel							•	
Vessel	Other (spec.)						<u> </u>		

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Additional Con	
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<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer EUP-C511

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application					le of Operati	V	<del></del>
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic						<u>"</u>	
	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)						1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)						· ·	
Fetal Imaging	Neonatal Cephalic		l	<u>†</u>				
								-
& Other	Trans-rectal							
	Trans-vaginal			<u> </u>				
	Trans-urethral		<u> </u>					
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)			<u> </u>				
	Intra-luminal							
	Other (spec.)		<u> </u>					
	Cardiac Adult	P	P	P		P	P	P
Cardiac	Cardiac Pediatric	P	P	P		P	P P	P
	Trans-esophageal (card.)							
	Other (spec.)						]	
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.)	. Troo		<u> </u>				

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Additional	Comments
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\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-C514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application			•	Mod	le of Operati	ion	
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P _	P		P	P	<u>P</u>
i	Abdominal	Pa	Pa_	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra operative (Neuro.)							
	Laparoscopic					•11		
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic						<u> </u>	
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal							
	Trans-vaginal		<u> </u>	<u></u>				
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal			1				
	Other (spec.)			<u> </u>	1			
	Cardiac Adult			<u> </u>				
Cardiac	Cardiac Pediatric			<u>.                                    </u>				
	Trans-esophageal (card.)		<u> </u>	<del> </del>	<u> </u>			
	Other (spec.)							
Peripheral	Peripheral vessel			<u> </u>	<u> </u>		ļ	
Vessel	Other (spec.)			1	<u> </u>			

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<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

System:

HI VISION Ascendus

EUP·C524 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic						Ì		
	Fetal	Р	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Spec.)								
	Intra operative (Neuro.)		Ĺ						
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc	
	Neonatal Cephalic								
Fetal Imaging									
& Other	Trans-rectal								
	Trans-vaginal			<u> </u>					
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)						ŀ		
	Musculo-skel. (Superfic.)								
	Intra luminal								
	Other (spec.)				_				
	Cardiac Adult								
Cardiac	Cardiac Pediatric					-			
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.)								

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Additional	Comments:
AGGILLIONAL	Comments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging

System:

HI VISION Ascendus

Transducer:

EUP-C532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
****	Fetal									
	Abdominal	Pa	Pa	Pa	·	Pa	Pa	Pa		
	Intra operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb		
	Intra-operative (Neuro.)						<u> </u>			
	Laparoscopic									
	Pediatric	P	P	P		P	P	P		
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd		
	Neonatal Cephalic	P	P	P		P	P	P		
Fetal Imaging	Adult Cephalic			<u> </u>						
& Other	Trans-rectal			<u> </u>						
	Trans-vaginal				<u> </u>					
	Trans-urethral									
	Trans-esoph. (non-Card.)			<u> </u>						
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)		L							
	Intra-luminal						•			
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)							_		
	Other (spec.)									
Peripheral	Peripheral vessel	P	P	P		P	P	P		
Vessel	Other (spec.)									

N = new indication. P = previously cleared in K093466

Additional	Comments:
Additiona	i Comments.

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b"	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, penis.
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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-C715

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	P	P	P		P	P	P		
i	Abdominal	Pa	Pa	Pa		Pa.	Pa	Pa		
	Intra operative (Spec.)		-			-		_		
	Intra operative (Neuro.)									
	Laparoscopic						•			
	Pediatric .	_ P	P	P		P	P	P		
	Small Organ (Spec.)	Pd	Pd	Pd	-	Pd	Pd	Pd		
	Neonatal Cephalic									
	Adult Cephalic									
& Other	Trans-rectal					<u> </u>				
	Trans-vaginal	-								
	Trans-urethral			L						
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)						T	-11.		
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult						1			
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)					· <del>-</del>				
	Peripheral vessel									
Vessel	Other (spec.)									

N = new indication. P = previously cleared in K093466

A 3 3 (4)	0
Additional	Comments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
_	(including amniocentesis).
Subscript "b":	
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
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Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: \_\_\_

Prescription Use (Per 21 CFR 801.109)

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP CC531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	P	P	P		P	P	P		
	Abdominal									
	Intra-operative (Spec.)		_		<u> </u>					
	Intra operative (Neuro.)									
	Laparoscopic						<u> </u>	<del></del>		
	Pediatric									
	Small Organ (Spec.)				l					
	Neonatal Cephalic			<u> </u>						
Fetal Imaging	Adult Cephalic									
& Other	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe		
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf		
	Trans-urethral			.						
	Trans-esoph. (non-Card.)			ļ						
	Musculo-skel. (Convent.)		ļ	<u> </u>						
	Musculo-skel. (Superfic.)			ļ	<u> </u>					
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult			]						
Cardiac	Cardiac Pediatric				ļ					
	Trans-esophageal (card.)							_		
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)						l			

N = new indication. P = previously cleared in K093466

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-CV524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	. Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	P	Р	P		P	P	P		
	Abdominal	P	P	P		P	P	P		
	Intra-operative (Spec.) Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P		
	Small Organ (Spec.)	P	P	P		P	P	P		
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic									
& Other	Trans-rectal	- "					<u> </u>			
	Trans-vaginal									
	Trans-urethral					··-				
	Trans-esoph. (non-Card.)		I	<u> </u>						
	Musculo-skel. (Convent.)						ļl			
	Musculo-skel. (Superfic.)			ļ						
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult			<u> </u>						
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)			ļ			ļ			
	Other (spec.)			<u> </u>	ļ	_				
Peripheral	Peripheral vessel		<u> </u>							
Vessel	Other (spec.)	· Tro	L				<u></u>			

N = new indication. P = previously cleared in K093466

Additiona	1 Com	ments:
Audilione	u vviii	michies.

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

System:

HI VISION Ascendus

Transducer:

EUP-CV714

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clin	ical Application	Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic				ļ.			
	Fetal	P	P	P		Р _	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)						Ü.	
•	Intra operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic			<u> </u>				
Fetal Imaging			ļ					
& Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral			į				
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	•		<u> </u>				
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)		<u> </u>				<u> </u>	
	Cardiac Adult			1				
Cardiac	Cardiac Pediatric							
	Trans esophageal (card.)			<u> </u>				
	Other (spec.)							
Peripheral	Peripheral vessel				<b></b>		ļ	
Vessel	Other (spec.)		20.400				<u> </u>	

N = new indication. P = previously cleared in K093466

Ad	ldition	al Con	iments:
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Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
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Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

System:

HI VISION Ascendus

Transducer: EUP-CV724

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application				Mode of Operation			
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic	•						
& Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	_						
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)					•		
Peripheral	Peripheral vessel		·					
Vessel	Other (spec.)		L	l				

N = new indication. P = previously cleared in K093466

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Addition	шаг	$_{\rm COIII}$	men	

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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510(k) Number:

Prescription Use (Per 21 CFR 801.109)

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

System:

HI VISION Ascendus

Transducer:

EUP-ES52E

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	ition Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined*	Other** (Spec.)
Ophthalmic	Ophthalmic	-						
	Fetal Abdominal							
	Intra-operative (Spec.) Intra-operative (Neuro.)					~		
	Laparoscopic							
	Pediatric Small Organ (Spec.)							
7. 17	Neonatal Cephalic							
Fetal Imaging & Other	Adult Cephalic Trans-rectal		ļ					
	Trans-vaginal					-		
	Trans-urethral Trans-esoph. (non-Card.)		-			-,		
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)		ļ					
	Intra-luminal Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric Trans-esophageal (card.)	P .	P	P	P	P	P	P
	Other (spec.)			İ .				
Peripheral	Peripheral vessel							
Vessel	Other (spec.)		l			<u>.</u>		

	Additional	Comments:
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Subscript "a"	Includes imaging for guidance of percutaneous blopsy of abdoluthar organs and structures
	(including amniocentesis).
Subscript "b";	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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N = new indication. P = previously cleared in K093466
\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Tissue Doppler imaging

System: Transducer: HI VISION Ascendus

EUP-ES52M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic		İ					
	Fetal			i -				
	Abdominal					· · ·		
	Intra-operative (Spec.)						1	
	Intra-operative (Neuro.)			Ι				
	Laparoscopic		]	] ""				
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic		İ					
	Adult Cephalic						-	
& Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral					_		
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra·luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							-
	Trans-esophageal (card.)	P	. P	P	P	P	P	P
	Other (spec.)				i			
	Peripheral vessel							
Vessel	Other (spec.)	· 1707	2 1 2 2					

N = new indication. P = previously cleared in K093466

Additiona	1 Com	mente:
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Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h"	Includes imaging for guidance of transrectal biopsy.

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510(k) Number:\_

Prescription Use (Per 21 CFR 801.109)

<sup>\*</sup>Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Tissue Doppler imaging

System:

HI VISION Ascendus

Transducer:

EUP-F334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application					le of Operati		
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
	Ophthalmic							
	Fetal							
	Abdominal			ļ				7.
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	_Pb
	Intra-operative (Neuro.)			<u> </u>				
	Laparoscopic	-					ļ	
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic	P	P	P		P	P	P
Fetal Imaging	Adult Cephalic			<u> </u>				
& Other	Trans-rectal	P	P	P	<u> </u>	P	P	P
	Trans vaginal	P	P	P		_ P	P	P
	Trans-urethral			<u> </u>				
	Trans-esoph. (non-Card.)						_	
	Musculo-skel. (Convent.)				ļ	,		
	Musculo skel. (Superfic.)		<u> </u>	<u> </u>			<u> </u>	
	Intra-luminal						_	
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric			1			<u> </u>	
	Trans-esophageal (card.)				<u>. </u>			
<u> </u>	Other (spec.)			<u> </u>				
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.)			1				

N = new indication. P = previously cleared in K093466

Additional Com	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: \_\_

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System:

HI VISION Ascendus

EUP·F531 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	Diagnostic ultrasound imag	ing or	iiuiu II	m aman						
	ical Application	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal							<u></u>		
	Abdominal	P	P	P		P	P	P		
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	·Pb		
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P		
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc		
	Neonatal Cephalic	P	P	P		P	P	P		
Fetal Imaging		-								
& Other	Trans-rectal	P	P	P		P	P	Ρ.		
	Trans-vaginal	P	P	P		P	P	P		
}	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult		L							
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel	_ P	P	P		P	P	P		
Vessel	Other (spec.)									

N = new indication. P = previously cleared in K093466

Additional (	Comments
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Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging

System:

HI VISION Ascendus

Transducer:

EUP-L52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application				Mod	le of Operati		
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
	Ophthalmic							
	Fetal							
·	Abdominal	Pa	Pa	Pa	1	Pa	Pa	Pa
	Intra-operative (Spec.)			<u> </u>				
	Intra-operative (Neuro.)						,,,,	
,	Laparoscopic			ļ				
1	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic			<u> </u>				
Fetal Imaging	Adult Cephalic						.,,	
& Other	Trans-rectal							
	Trans-vaginal			<u> </u>	1 —			
İ	Trans-urethral			<u> </u>		*****		
	Trans-esoph. (non-Card.)				L			
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo skel. (Superfic.)							
	Intra·luminal			<u> </u>				
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric		1	<u> </u>				
	Trans-esophageal (card.)					<u></u>		
	Other (spec.)		L		<u> </u>			
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.)			.l				

N = new indication. P = previously cleared in K093466

Additional Con	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
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Division of Reproductive, Abdominal, ENT, and Radiological Devices

and Radiological Devices

510(k) Number: <u>人口い</u>

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System: Transducer: HI VISION Ascendus

EUP·L53

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clin	ical Application				Mod	le of Operati	on	
General (Track I only)		В	M	PWD	CWD	Color Doppler	Combined*	Other** (Spec.)
Ophthalmic	Ophthalmic						1	
	Fetal .							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra operative (Spec.)							
	Intra-operative (Neuro.)						1	
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal							
	Trans-vaginal					<u> </u>		-
	Trans-urethral		ļ			<del>-</del>		
	Trans-esoph. (non-Card.)						_	
	Musculo skel. (Convent.)	P	P	P		P	P	P
	Musculo skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal					•		
	Other (spec.)							•
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							-
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.)							

N = new indication. P = previously cleared in K093466

Addition	-1 C			٠	
Addition	ar Co	$\mathbf{mm}$	en	LS.	

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<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System:

Transducer:

HI VISION Ascendus EUP-L53L

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal					P	P	P			
	Abdominal	P	P	P		P	+ P	<u> </u>			
	Intra-operative (Spec.)	_			<b>_</b>		· · · · · · · · · · · · · · · · · · ·				
	Intra-operative (Neuro.)			<u> </u>			<del> </del>				
	Laparoscopic			<u> </u>			P	P			
	Pediatric	P	P	P		<u> </u>	Pc	Pc			
	Small Organ (Spec.)	Pc	Pc	Pc	<del>                                     </del>	Pc	PC	rc			
	Neonatal Cephalic			┞—			<del> </del>				
	Adult Cephalic	<u></u>	<u> </u>	<b></b>	<u> </u>		<del>                                     </del>	<del></del>			
& Other	Trans-rectal			<b>_</b>	ļ						
	Trans vaginal			<del>. </del>	1 —		ļ				
	Trans urethral				<del>                                     </del>						
	Trans-esoph. (non-Card.)	- 5	<del> </del>	<del>                                     </del>		P	P				
	Musculo-skel. (Convent.)	P	P_	P	<del>                                     </del>	P	P	P P			
	Musculo-skel (Superfic.)	P	P	P		r	<u> </u>				
	Intra-luminal		<del>                                     </del>	4.	ļ						
	Other (spec.)		<u> </u>	<del> </del>			_				
	Cardiac Adult		<del> </del>	<del> </del>	<b>_</b>		<del>- </del>				
Cardiac	Cardiac Pediatric	ļ		↓	ļ		<del> </del>	<u> </u>			
	Trans-esophageal (card.)		<b>_</b>	—-	<del> </del>		<del>-</del>				
	Other (spec.)		<del></del>		<del>                                     </del>		P	P			
Peripheral	Peripheral vessel	P	P	P	<del> </del>	P	P P	<u> </u>			
Vessel	Other (spec.)		00.400		<u> </u>	<u>L.                                    </u>					

N = new indication. P = previously cleared in K093466

Additional Con	nments
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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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510(k) Number: <u>}</u>

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System: Transducer: HI VISION Ascendus

EUP-L54MA

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	Diagnostic ultrasound imag	ing or i	iiuiu II(	ow allaly			<del></del>				
	ical Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic		1								
	Fetal					•					
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa			
	Intra operative (Spec.)										
	Intra-operative (Neuro.)	•									
	Laparoscopic										
	Pediatric	P	P	P		P	P	P			
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd			
	Neonatal Cephalic										
	Adult Cephalic										
& Other	Trans-rectal										
	Trans-vaginal							-			
	Trans-urethral										
	Trans-esoph. (non-Card.)			L							
	Musculo-skel. (Convent.)	P	P	P		P	P	P			
	Musculo-skel. (Superfic.)	P	P	<u>P</u>		P	P	P			
	Intra-luminal	_									
	Other (spec.)		• .								
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)										
	Other (spec.)	, -									
	Peripheral vessel	P	P	P		P	P	P			
Vessel	Other (spec.)										

N = new indication. P = previously cleared in K093466

#### Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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Subscript "f":	Includes imaging for guidance of transyaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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510(k) Number: | |

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System:

HI VISION Ascendus

Transducer:

EUP-L65

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	P	P	P		P	P	Р	
'	Abdominal	P	P	P			- I	<u> </u>	
	Intra operative (Spec.)					-	4		
	Intra-operative (Neuro.)			<u> </u>	<del>                                     </del>		<del> </del>		
	Laparoscopic	P	P	P		P	P	P	
	Pediatric	Pc	Pc	Pc		Pc	Pc	Pc	
Fetal Imaging	Small Organ (Spec.)	P¢	Pc	PC		rc	FC	10	
	Neonatal Cephalic				<del>                                     </del>		<u> </u>		
			<u> </u>						
& Other	Trans-rectal					<del></del>		<del></del>	
,	Trans-vaginal				<u> </u>				
1	Trans-urethral			<del>                                     </del>	<del>                                     </del>				
	Trans-esoph. (non-Card.)	P	P	P		P	P	P	
Ì	Musculo-skel. (Convent.)	P	P	P		<u>г</u> Р	P	P	
Ì	Musculo skel (Superfic.)	P	P	r		г			
	Intra-luminal			<del> </del>			-		
	Other (spec.)		<u> </u>	<del> </del>	<u> </u>				
<b>2</b> 1.	Cardiac Adult		ļ		1	<del></del>	<u> </u>		
Cardiac	Cardiac Pediatric			<del> </del>	1				
	Trans-esophageal (card.)		<b> </b>	<del> </del>				_	
	Other (spec.)	D	<u> </u>	<del>                                     </del>		<u>\</u>	P —	P	
Peripheral	Peripheral vessel	P	P	P	<del> </del>	P	P	r	
Vessel	Other (spec.)		<u> </u>	<u> </u>	لبلل				

N = new indication. P = previously cleared in K093466

Additional Comments
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Subscript "a"	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT;

and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-L73S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)		В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
Оргонично	Fetal Abdominal Intra operative (Spec.) Intra operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic	Pa P Pd	Pa P Pd	Pa P Pd		Pa P Pd	Pa P Pd	Pa P Pd		
Fetal Imaging & Other	Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)									
	Musculo skel. (Convent.) Musculo skel. (Superfic.) Intra luminal Other (spec.)	P P	P P	P		P P	P P	<u>Р</u> Р		
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)	_								
Peripheral Vessel	Peripheral vessel Other (spec.)	P	P	P		P	P	P		

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#### Additional Comments:

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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: \_\_\_\_/

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer EUP-L74M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa		
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)						<del>                                     </del>			
	Laparoscopic									
	Pediatric	P	P	P		P	P	P		
Fetal Imaging	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd		
	Neonatal Cephalic									
				<u> </u>						
& Other	Trans-rectal			<u> </u>						
	Trans-vaginal			<u> </u>			<u> </u>			
	Trans-urethral									
	Trans-esoph. (non-Card.)				<u> </u>		<del>                                     </del>			
	Musculo-skel. (Convent.)	P	P	P		P	P	P		
	Musculo-skel. (Superfic.)	P	P	P	<b></b>	P	P	P		
	Intra-luminal			ļ	<u> </u>		1			
	Other (spec.)			<u> </u>	<b></b>					
	Cardiac Adult			<u> </u>	<b>  </b>					
Cardiac	Cardiac Pediatric			<del>  -</del>						
	Trans-esophageal (card.)			<b></b>						
	Other (spec.)			<u> </u>	<u> </u>					
Peripheral	Peripheral vessel	P	P	P		P	P	P		
Vessel	Other (spec.)	l	ļ	<u> </u>			/			

N = new indication. P = previously cleared in K093466

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
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Subscript "g":	For pediatric patients.
Subscript "ĥ":	
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and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

EUP-L75 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic							•	
	Fetal Abdominal Intra operative (Spec.) Intra operative (Neuro.)	Pa	Pa	Pa		Pa	Pa	Pa	
Fetal Imaging & Other	Laparoscopic Pediatric Small Organ (Spec.)	P Pd	P Pd	P Pd		P Pd	P Pd	P Pd	
	Neonatal Cephalic Adult Cephalic Trans-rectal		10			<u></u>	10	- Fu	
	Trans-vaginal Trans-urethral								
	Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.)	P P	P P	P		P P	P P	P P	
	Intra·luminal Other (spec.)								
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.)								
Peripheral Vessel	Other (spec.) Peripheral vessel Other (spec.)	Р	P	P		Р -	P	P	

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#### Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
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Subscript "g":	For pediatric patients.
	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Subscript "e": Subscript "f": Subscript "g": Subscript "h":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  Includes imaging for guidance of transrectal biopsy.  Includes imaging for guidance of transvaginal biopsy.  For pediatric patients.  Includes imaging for guidance of transrectal biopsy.  E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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and Radiological Devices

510(k) Number:

Prescription Use (Per 21 CFR 801.109)

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus

Transducer:

EUP-LV74

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Spec.)						ļ		
	Intra-operative (Neuro.)								
	Laparoscopic						7	- TD	
	Pediatric	P	P	P		P	P	P	
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc	
Fetal Imaging	Neonatal Cephalic		<u> </u>	ļ <u> </u>					
& Other	Trans-rectal		<u> </u>	<u> </u>			i		
,	Trans vaginal			ļ	ļ		<u> </u>		
	Trans-urethral			ļ	ļ		<u> </u>		
	Trans-esoph. (non-Card.)		ļ				<u> </u>	P	
	Musculo-skel. (Convent.)	P	P_	P	1	P	P		
	Musculo-skel. (Superfic.)	P	P	P	<b>└</b>	P	P	P	
	Intra-luminal		<u>,                                     </u>	<del> </del>					
	Other (spec.)								
	Cardiac Adult		Ļ	<u> </u>			ļ		
Cardiac	Cardiac Pediatric	<u> </u>	<u> </u>	ļ	ļi	·			
	Trans-esophageal (card.)		<u> </u>	<del> </del>			_	'	
	Other (spec.)	<u> </u>	<u> </u>				<u></u>	<del></del>	
Peripheral	Peripheral vessel	P	P	P		<u>P</u>	P	P	
Vessel	Other (spec.)		20100	.]			1		

N = new indication. P = previously cleared in K093466

Additional Com	ments.
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Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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and Radiological Devices

510(k) Number: \_\_

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Real Time Tissue Elastography

System:

HI VISION Ascendus

Transducer:

EUP-O53T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic .						<del>  </del>			
Fetal Imaging & Other	Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	Pb	Pb	Pb		Pb	Pb	Pb		
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)									

N = new indication. P = previously cleared in K093466

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System:

HI VISION Ascendus

Transducer:

EUP-O54J

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
	Abdominal								
	Intra-operative (Spec.)	Pb	Pb_	Pb		Pb	Pb	Pb	
	Intra operative (Neuro.)						<u> </u>		
	Laparoscopic						.]		
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)			-					
i	Musculo-skel. (Convent.)	P	P	P		P	P	P	
İ	Musculo-skel. (Superfic.)	P	P	P		P	P	P	
	Intra-luminal								
	Other (spec.)								
	Cardiac Adult						<del> </del>		
Cardiac	Cardiac Pediatric			ļ <u>.</u>			<b>-</b>		
	Trans esophageal (card.)		ļ	<u> </u>			1		
	Other (spec.)		- T		1	- D	D	P	
Peripheral	Peripheral vessel	P	P	P		P	P	- P	
Vessel	Other (spec.)			<u> 1—</u>					

N = new indication. P = previously cleared in K093466

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d"	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: <u>よいし</u>してろ

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System: Transducer: HI VISION Ascendus

EUP-O732T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic						<del>                                     </del>	<del></del>	
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	P	P	P		P	P	P	
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)								
Peripheral Vessel	Peripheral vessel Other (spec.)	· IVoc							

N = new indication. P = previously cleared in K093466

Subscript "a":	
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System:

Transducer:

HI VISION Ascendus EUP-OL334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
ı	Abdominal								
	Intra operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic	P	P	P		P	P	P	
	Pediatric								
	Small Organ (Spec.)						<u>                                       </u>		
	Neonatal Cephalic		1						
Fetal Imaging	Adult Cephalic					•			
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)		ļ	1					
	Musculo-skel. (Convent.)			ļ					
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)								
	Cardiac Adult						J	****	
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)		<u> </u>	ļ					
	Other (spec.)		1						
Peripheral	Peripheral vessel			1					
Vessel	Other (spec.)								

N = new indication. P = previously cleared in K093466

A 1 1'4' 1	^
Additional	Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System:

HI VISION Ascendus

EUP-R54AW-19, -33 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined*	Other** (Spec.)	
Ophthalmic	Ophthalmic							•	
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal	P	P	P		P	P	P	
Cardiac Peripheral	Other (spec.) Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.) Peripheral vessel					_			

N = new indication. P = previously cleared in K093466

Additional	Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

Concurrence of CDRH, Office of Device Evaluation (ODE)

and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

System -

HI VISION Ascendus

Transducer:

EUP-S50A

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	P	P	P	P	P	P	P		
•	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa		
	Intra-operative (Spec.) Intra-operative (Neuro.)	•						-		
	Laparoscopic									
	Pediatric	P	P	P	P	Р	P	P		
	Small Organ (Spec.)									
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic	P	P	P	P	P	P	P		
& Other	Trans-rectal									
	Trans vaginal									
	Trans-urethral							<del>.</del> .		
	Trans-esoph. (non-Card.)			1			·			
	Musculo-skel. (Convent.)						<u> </u>			
	Musculo-skel. (Superfic.)						<u> </u>			
	Intra-luminal		_							
	Other (spec.)					•••				
	Cardiac Adult	P	P	P	P	P	P	P		
Cardiac	Cardiac Pediatric	P	P	P	P	P.	Р	P		
	Trans-esophageal (card.)									
	Other (spec.)			l						
Peripheral	Peripheral vessel	P	P	P	P	P	P	P		
Vessel	Other (spec.)									

N = new indication. P = previously cleared in K093466

Additional Con	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: 4110473

Prescription Use (Per 21 CFR 801.109)

<sup>\*</sup>Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Tissue Doppler Imaging

System:

HI VISION Ascendus

EUP-S52 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General	Specific	В	M	PWD	CWDI	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)	Б	IVI	FWD	CWD	Doppler	(Spec.)		
			ļ			Doppier	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
	Fetal		<u> </u>					_	
	Abdominal						<u></u>		
	Intra-operative (Spec.)								
1	Intra-operative (Neuro.)			<b>!</b>					
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	
	Small Organ (Spec.)	Pc	Pc	Pc	Pc	Pc	Pc	Pc	
1	Neonatal Cephalic							-	
Fetal Imaging	Adult Cephalic								
& Other	Trans-rectal								
1	Trans vaginal						1		
	Trans-urethral								
	Trans-esoph. (non-Card.)						T		
į	Musculo-skel. (Convent.)								
i	Musculo-skel. (Superfic.)			<del>                                     </del>					
	Intra-luminal						1		
	Other (spec.)			1			† <u>-</u>		
	Cardiac Adult								
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans-esophageal (card.)				<del></del>		<del>                                     </del>		
1	Other (spec.)			_			1		
Peripheral	Peripheral vessel						†	•	
Vessel	Other (spec.)		<del> </del>	<del> </del>		•	<del>                                     </del>		
: 20001	0 51102 (0 p 0 0.)						<u> </u>		

N = new indication. P = previously cleared in K093466

	_
Additional	Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
_	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: <u>| 人</u>! しし

<sup>\*</sup>Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Tissue Doppler imaging

System:

HI VISION Ascendus

Transducer:

EUP-S70

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	P	P	P	Р	P	P	P	
	Abdominal	P	P	P	P	P	P	P	
	Intra operative (Spec.)			Ĭ					
	Intra operative (Neuro.)								
	Laparoscopic								
:	Pediatric	P.	P	P	P	P	P	P	
	Small Organ (Spec.)						<u> </u>		
	Neonatal Cephalic							· <del></del>	
Fetal Imaging	Adult Cephalic	P _	P	P	P	P	P	P	
& Other	Trans-rectal								
	Trans-vaginal						1		
	Trans-urethral						1		
	Trans-esoph. (non-Card.)						<u></u>		
	Musculo-skel. (Convent.)								
	Musculo skel. (Superfic.)								
	Intra-luminal							."	
	Other (spec.)						1		
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	
	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans-esophageal (card.)			<u> </u>					
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P	P	P	P	P	
Vessel	Other (spec.)								

N = new indication. P = previously cleared in K093466

Additional Con	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b"	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Tissue Doppler Imaging

System:

HI VISION Ascendus

Transducer-

EUP·S72

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Huld flow analysis if the numan body as follows.							
		Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
	Fetal					*			
İ	Abdominal	P	P	P	P	P	P	P	
•	Intra operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic							- 10	
	Pediatric	P	P	P	P	P	P	P	
	Small Organ (Spec.)		[	1					
	Neonatal Cephalic	_ P	P	P	P	P	P	P	
	Adult Cephalic								
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral			l 3					
	Trans-esoph. (non-Card.)			1. —					
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)								
	Cardiac Adult	P	P	P	P	P	P	P	
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.)					·			
7									

N = new indication. P = previously cleared in K093466

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	

Subscript "f" Includes imaging for guidance of transvaginal biopsy. Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off) Division of Reproductive, Abdominal, ENT,

and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Tissue Doppler imaging\_

System:

HI VISION Ascendus

Transducer:

EUP-U533

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

			ing or fluid flow analysis if the numan body as follows:							
Clin	ical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic							<u> </u>		
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	Ph	Ph	Ph		Ph	Ph	Ph		
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)									

N = new indication. P = previously cleared in K093466

Additiona	I CO	mments.
Cubagains	H H .	Includo

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b"	Includes imaging of organs and structures exposed during surgery
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Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: 1人110673

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System: Transducer: HI VISION Ascendus

EUP-V53W

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	_ P	P	ľ	P	P	Ρ.
	Abdominal							
	Intra operative (Spec.)					<del>-</del>		
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric						<u> </u>	
	Small Organ (Spec.)							
	Neonatal Cephalic						1 -	
Fetal Imaging	Adult Cephalic						1	·
& Other	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)			1				
	Musculo skel. (Convent.)			]				
	Musculo-skel. (Superfic.)							-
	Intra-luminal			Ĺ	· Ţ.			
	Other (spec.)						]	•
	Cardiac Adult							•
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)	. ,						<u> </u>
	Other (spec.)							
Peripheral	Peripheral vessel					-	i i	_
$V_{\rm essel}$	Other (spec.)						· · ·	

N = new indication. P = previously cleared in K093466

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d"	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

System:

HI VISION Ascendus
EUP-VV531

Transducer:

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ded use. Diagnostic ultresound imaging or fluid flow analysis if the human hody as follows:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the huma								
· Clin	ical Application				Mod	le of Operati	on	
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic .			i				
	Fetal	P	P	P		P	P	P
	Abdominal						· -	
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)						<u> </u>	
	Neonatal Cephalic			]			<u> </u>	
Fetal Imaging	Adult Cephalic				<u> </u>			
& Other	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)			<u> </u>				
	Musculo-skel. (Convent.)				11		<u> </u>	
	Musculo-skel. (Superfic.)							
	Intra-luminal		L					
	Other (spec.)		ļ		<u> </u>			
	Cardiac Adult				1			
Cardiac	Cardiac Pediatric			ļ				
	Trans esophageal (card.)		ļ	ļ	<b> </b>		<del> </del>	
	Other (spec.)		<b>↓</b>	<u> </u>	ļ		1	
Peripheral	Peripheral vessel				11	.,,		<u> </u>
Vessel	Other (spec.)		<u> </u>					

Additional Con	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b"	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: <u>人</u>いし

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D imaging

System:

HI VISION Ascendus

Transducer: EUP-VV731

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							-
	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)						1	
	Intra-operative (Neuro.)							
!	Laparoscopic						T 7	
	Pediatric						_	
	Small Organ (Spec.)			]				
	Neonatal Cephalic				1			
	Adult Cephalic		_					
& Other	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	_ P		P	P	P
	Trans-urethral		·					
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	_					1 -	
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel						i i	
Vessel	Other (spec.)							

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Add	itions	ıl Con	mante

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<sup>\*</sup>Combination of each operating mode, B, M, PWD and Color Doppler.

<sup>\*\*</sup>Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D imaging